

REMARKS

In the Office Action dated March 30, 2009, the Examiner states that because claims 26-27 newly added in the Response filed on January 12, 2009 present a separate group of invention, the Examiner has modified the previous restriction requirement by adding Group VI. Specifically, the Examiner contends that the application presently contains the following groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- Group I Claims 1-17, and 20, in part, drawn to a method of genotype comprising RNA or DNA from connexion 26.
- Group II Claims 1-17, and 20, in part, drawn to a method of genotype comprising RNA or DNA from pendrin.
- Group III Claims 1-17, and 20, in part, drawn to a method of genotype comprising RNA or DNA from mitochondrial 12s rRNA.
- Group IV Claims 1-17, and 20, in part, drawn to a method of genotyping comprising RNA or DNA from usherin.
- Group V Claims 21-25, drawn to a set of one or more oligonucleotides and a kit.
- Group VI Claims 1-17, 20, in part, and 26-27¹, drawn to a method of genotyping comprising RNA or DNA from connexion 26, pendrin, mitochondrial 12s rRNA, and usherin.

Further, the Examiner states that if one of Groups I-IV or VI is elected, Applicants must further elect a specific sequence from SEQ ID NOS: 1-64.

In order to be fully responsive to the Examiner's Requirement for Restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group VI, claims 1-17, 20, in part, and claims 26-27, drawn to a method of genotyping based on the combination

¹ The Examiner mistakenly omitted claims 26-27 from Group VI on page 3 of the Office Action. Applicants' representative confirmed by telephone that the Examiner meant to include claims 26-27 in Group VI.

of connexin 26, pendrin, mitochondrial 12s rRNA, and usherin. Applicants further provisionally elect SEQ ID NO: 1 as the elected sequence for continued prosecution.

However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

The Examiner alleges that the inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Specifically, the Examiner contends that the technical feature, which is shared by Groups I-VI, is a genotyping method to detect deafness mutations. The Examiner notes that Hone et al. (*Otolaryngology Clinics of North America* Vol 35 p. 751, 2002) teach a genotyping method to detect deafness mutations of connexin. Therefore, the Examiner concludes that a genotyping method to detect deafness mutations fails to make a contribution over the prior art; and thus there is no special technical feature that links Groups I-VI.

Applicants respectfully submit that unity of invention is the issue at hand. The Examiner should not rely on an evaluation of novelty or unobviousness based on the prior art in order to determine whether the requirement of unity of invention is satisfied under PCT Rule 13.1. Applicants should be given the opportunity to argue on merits during prosecution whether the claims are patentable over the prior art. For example, Applicants note that the cited reference does not teach a genotyping method based on a combination of connexin 26, pendrin, mitochondrial 12s rRNA, or usherin. Restriction of the claims at this stage would deny Applicants such an opportunity.

Further, Applicants respectfully submit that a requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: “The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (‘requirement of unity of invention’).” (Emphasis added.) PCT Rule 13.2 states: “The expression ‘technical features’ shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.” (Emphasis added.) In the present case, the listed groups of invention are linked together by the single inventive concept that a genotyping method of a relevant pathological condition is achieved by employing at least one allele specific oligonucleotide which covers a mutation selected from connexin 26, pendrin, mitochondrial 12s rRNA or usherin. In certain preferred embodiments, a combination of some or all of these genes can be employed as a basis of genotyping.

Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined groups, one from another, as presented by the Examiner.

Accordingly, it is respectfully submitted that the present claims (claims 1-17 and 20-27) satisfy the requirement for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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